

From: [Henry Kahn](#)
To: white.paul@epamail.epa.gov
Cc: [Jennifer Jinot/DC/USEPA/US@EPA](#); [Nagu Keshava/RTP/USEPA/US@EPA](#); [Sury Vulimiri](#); [Bob Sonawane](#)
Subject: draft of ethylene oxide assessment
Date: 04/10/2009 04:28 PM
Attachments: [Carcinogenicity Ethylene Oxide - 10Apr09_HK_2.doc](#)

Paul,

Attached is the draft of the ethylene oxide assessment. The major sections of the document dealing with genotoxicity and dose response analysis have been revised. These are sections 3.3.2 Genotoxicity (this section was titled 'Mutagenicity' previously) and 3.4 Mode of Action that were written by Nagu and Sury. There some notes highlighted in these sections where I have asked Nagu and Sury to add material and/or answer questions. Nagu said they would have responses to these notes by Monday. This draft also contains a new section 4. 'Cancer dose response relationship for inhalation exposure' written by Jennifer which also has highlighted notes that will be addressed when Jennifer returns next week.

The other sections of the document still need review and editing including the executive summary has not yet been revised. The draft summary of external peer review and public comments (Appendix G) is in process but not included in the attached

The assessment also has (or will have) the following new or re-labelled appendices. This is in draft so please bear with the formatting and pagination which needs considerable work.

- Appendix A - Critical Review of Epidemiological Evidence
- Appendix B - References for Figure 3-3
- Appendix C - Steenland analysis report
- Appendix D - Life Table analysis
- Appendix E - Weighted linear regression analysis of categorical exposure response following Rothman 1986
- Appendix F - Model parameters from analysis of animal tumor incidence
- Appendix G - Summary of external peer review and public comments



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Carcinogenicity Ethylene Oxide - 10Apr09_HK_2.doc

From: [Terri Konoza](#)
To: [Jennifer Jinot](#)
Cc: [David Bussard](#); [Gina Perovich](#); [Paul White](#); [Henry Kahn](#)
Subject: Re: EtO materials - one other...
Date: 11/15/2010 03:46 PM
Attachments: [Carcinogenicity Ethylene Oxide - FinalDraft - 12nov2010.doc](#)

When I worked on this Friday, I focused on cleaning up the TOC. At that time, I did not notice that the footer date throughout the document was dated July. I changed the footer date and made a few other changes: replaced "Final Draft" on title page to "Review Draft"; replaced the disclaimer with our standard disclaimer for draft documents, and made few other minor adjustments.



Carcinogenicity Ethylene Oxide - FinalDraft - 12nov2010.doc

▼ Jennifer Jinot---11/12/2010 06:28:34 PM---hi, David. here are the clean final copies of the usual 4 items required. can you please provide s

From: Jennifer Jinot/DC/USEPA/US
To: David Bussard/DC/USEPA/US@EPA
Cc: Gina Perovich/DC/USEPA/US@EPA, Paul White@EPA, Henry Kahn/DC/USEPA/US@EPA
Date: 11/12/2010 06:28 PM
Subject: EtO materials - one other...

hi, David. here are the clean final copies of the usual 4 items required. can you please provide some more guidance about what you need for the supplemental item of the "one-pager on what new work has been done since SAB review" and what the purpose of it is? e.g., do you want all the new work that was done since the SAB review or just the things that are different in the assessment since the SAB review? is the focus on bottom-line findings or all new work (or differences in the assessment)? do you want it as a comparison or just an embellished list of the new (or different) stuff? is it to be part of the materials we're providing to the IO in advance? thanks. jj

[attachment "Carcinogenicity Ethylene Oxide - FinalDraft - 12nov2010.doc" deleted by Terri Konoza/DC/USEPA/US] [attachment "EPA-SAB-08-004-unsigned.pdf" deleted by Terri Konoza/DC/USEPA/US] [attachment "FACT SHEET - Final - Ethylene Oxide 9 Nov 2010.doc" deleted by Terri Konoza/DC/USEPA/US] [attachment "IRISsummaryEtO-Final-12Nov2010.doc" deleted by Terri Konoza/DC/USEPA/US]

p.s. much thanks to Terri Konoza who stayed late today to update the various tables of contents for the assessment!

▼ David Bussard---11/12/2010 02:21:20 PM---Other thing we'll need is a one-pager on what new work has been done since SAB review, so we can hav

From: David Bussard/DC/USEPA/US
To: Jennifer Jinot/DC/USEPA/US@EPA, Paul White@EPA
Cc: Gina Perovich/DC/USEPA/US@EPA
Date: 11/12/2010 02:21 PM
Subject: Fw: EtO materials - one other...

Other thing we'll need is a one-pager on what new work has been done since SAB review, so we can have that discussion of comfort with not needing any additional review. As part of that, I'd like us to note whether Leslie Staynor (or Leslie with co-authors here?) is writing up any of the work on the spline modeling and if so what is the status of that manuscript?

David

----- Forwarded by David Bussard/DC/USEPA/US on 11/12/2010 02:19 PM -----

From: David Bussard/DC/USEPA/US
To: Paul White@EPA, Jennifer Jinot/DC/USEPA/US@EPA
Date: 11/12/2010 02:18 PM
Subject: EtO materials

Paul and Jennifer,

I'd like to have all the EtO materials soon. I'd like to spot check them and then send on to the IO before we brief them on this coming Thursday.

I think the list is as follows:

- Assessment we think is ready for IO review.
- Factsheet we think is ready
- IRIS Summary
- electronic copy of SAB peer review report

When do you think I'll have all of those?

David

From: [David Bussard](#)
To: [Robert Kavlock](#)
Cc: [Cheryl Scott](#); [Jennifer Jinot](#); [Kenneth Olden](#); [Flowers.Lynn@epamail.epa.gov](#); [Charles Ris](#); [Gina Perovich](#); [clark.becki@epamail.epa.gov](#); [Vincent Cogliano](#)
Subject: EtO documents you requested
Date: 09/19/2012 12:56 PM
Attachments: [EtO_Carcinogenicity_Support_Doc_14aug2012-FOR EDITING-andbeyond.doc](#)
[steenland2004.pdf](#)
[Steenland2003-epi-breastCA.pdf](#)

Bob,

Here is the latest draft of the EtO assessment. It reflects work we did to clarify topics after discussions with OPP, and is the version we sent to final "tech edit" (which hopefully is mostly minor formatting, footnote checking, etc..)

- There is an overview of the model results in the Executive Summary - for example, page 1-2 thru page 1-6 (also can be identified as pages 19 thru 23 if using the Word program pages rather than the page number typed on the document page).
-
- There is greater discussion in Chapter 4. I find the figures (such as figure 4-1 on page 4-9, figure 4-2 on page 4-18, etc, and the figures in the briefing package we gave to you and Lek) to be useful when reading the text discussion of judgments.
-
- Appendix D has detailed discussions of the modeling.
-
- Appendix H has the responses to peer review and public comments.



Also attached here are some of the papers for the NIOSH study - the most recent mortality follow-up study and the breast cancer incidence study, and the link for HERO. If you can't find specific references that he would like to look at in HERO or if that is just too inconvenient, you can contact Jennifer Jinot (or any of us) for any of the papers you want and we can send you a pdf. In theory, you can access other cited papers in HERO under LitBrowser. The link for HERO for EPA staff is: <https://ssoprod.epa.gov/sso/jsp/HEROlogin.jsp>. But, that may not be the best way for you to use your time. So, let us know if you want us to send you something.



If you want more, we can link you to the SAB Report or send you OPP comments

(primarily post formal Agency-review) and some of the materials we used in discussions with them.

David Bussard